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BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **GARFIELD BEACH CVS LLC** **DBA CVS PHARMACY No. 4789** PIC OMAR MARQUEZ (since 4/9/2014) 10945 Victory Blvd. North Hollywood, CA 91606 **Pharmacy Permit License No.** PHY 46783, and **OMAR MARQUEZ** 1775 N. Orange Dr., Apt. 204 Los Angeles, CA 90028 **Pharmacist License Number** RPH 69427, Respondents.	Case No. 5623 **A C C U S A T I O N**

Complainant alleges:

PARTIES

1. Virginia Herold (Complainant) brings this Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

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2. On or about July 27, 2004, the Board of Pharmacy issued Pharmacy Permit Number PHY 46783 to Garfield Beach CVS LLC dba CVS Pharmacy #4789 (Respondent Pharmacy). Omar Marquez, RPH 69427, is and has been the Pharmacist-in-Charge since April 9, 2014. The Pharmacy Permit was in full force and effect at all times relevant to the charges brought herein and will expire on June 1, 2016, unless renewed.

3. On or about August 26, 2013, the Board of Pharmacy issued Original Pharmacist License Number RPH 69427 to Omar Marquez (Respondent Marquez). The Pharmacist License will expire on July 31, 2017, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 4300 of the Code provides, in part, that every license issued by the Board is subject to discipline, including suspension or revocation.

6. Section 4300.1 of the Code states:

"The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license."

7. Section 4301 of the Code states, in part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . .

"(j) The violation of any of the statutes of this state, or any other state, or of the United States regulating controlled substances and dangerous drugs."

. . .

"(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency."

8. Section 4302 of the Code states:

"The board may deny, suspend, or revoke any license of a corporation where conditions exist in relation to any person holding 10 percent or more of the corporate stock of the corporation, or where conditions exist in relation to any officer or director of the corporation that would constitute grounds for disciplinary action against a licensee."

9. Section 4113 of the Code states, in part:

"(b) The pharmacist-in-charge shall be responsible for a pharmacy's compliance with all state and federal laws and regulations pertaining to the practice of pharmacy."

10. Section 4022 of the Code states

"Dangerous drug" or "dangerous device" means any drug or device unsafe for self-use in humans or animals, and includes the following:

"(a) Any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only," or words of similar import.

"(b) Any device that bears the statement: "Caution: federal law restricts this device to sale by or on the order of a _____," "Rx only," or words of similar import, the blank to be filled in with the designation of the practitioner licensed to use or order use of the device.

"(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

REGULATIONS

11. California Code of Regulations, title 16, section 1707.3, states:

"Prior to consultation as set forth in section 1707.2, a pharmacist shall review a patient's drug therapy and medication record before each prescription drug is delivered. The review shall include screening for severe potential drug therapy problems."

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12. California Code of Regulations, title 16, section 1707.2, states, in part:

"(b)(1) In addition to the obligation to consult set forth in subsection (a), a pharmacist shall provide oral consultation to his or her patient or the patient's agent in any care setting in which the patient or agent is present:

. . .

"(B) whenever a prescription drug not previously dispensed to a patient in the same dosage form, strength or with the same written directions, is dispensed by the pharmacy."

13. California Code of Regulations, title 16, section 1711, states, in part:

"(a) Each pharmacy shall establish or participate in an established quality assurance program which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors.

"(b) For purposes of this section, "medication error" means any variation from a prescription or drug order not authorized by the prescriber, as described in Section 1716. Medication error, as defined in the section, does not include any variation that is corrected prior to furnishing the drug to the patient or patient's agent or any variation allowed by law.

(c)(1) Each quality assurance program shall be managed in accordance with written policies and procedures maintained in the pharmacy in an immediately retrievable form.

(2) When a pharmacist determines that a medication error has occurred, a pharmacist shall as soon as possible:

(A) Communicate to the patient or the patient's agent the fact that a medication error has occurred and the steps required to avoid injury or mitigate the error.

(B) Communicate to the prescriber the fact that a medication error has occurred.

(3) The communication requirement in paragraph (2) of this subdivision shall only apply to medication errors if the drug was administered to or by the patient, or if the medication error resulted in a clinically significant delay in therapy.

(4) If a pharmacist is notified of a prescription error by the patient, the patient's agent, or a prescriber, the pharmacist is not required to communicate with that individual as required in paragraph (2) of this subdivision.

(d) Each pharmacy shall use the findings of its quality assurance program to develop pharmacy systems and workflow processes designed to prevent medication errors. An investigation of each medication error shall commence as soon as is reasonably possible, but no later than 2 business days from the date the medication error is discovered. All medication errors discovered shall be subject to a quality assurance review.

(e) The primary purpose of the quality assurance review shall be to advance error prevention by analyzing, individually and collectively, investigative and other pertinent data collected in response to a medication error to assess the cause and any contributing factors such as system or process failures. A record of the quality assurance review shall be immediately retrievable in the pharmacy."

14. California Code of Regulations, title 16, section 1761, states, in part:

"(a) No pharmacist shall compound or dispense any prescription which contains any significant error, omission, irregularity, uncertainty, ambiguity or alteration. Upon receipt of any such prescription, the pharmacist shall contact the prescriber to obtain the information needed to validate the prescription."

15. California Code of Regulations, title 16, section 1770, states:

"For the purpose of denial, suspension, or revocation of a personal or facility license pursuant to Division 1.5 (commencing with Section 475) of the Business and Professions Code, a crime or act shall be considered substantially related to the qualifications, functions or duties of a licensee or registrant if to a substantial degree it evidences present or potential unfitness of a licensee or registrant to perform the functions authorized by his license or registration in a manner consistent with the public health, safety, or welfare."

COST RECOVERY

16. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

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FACTUAL SUMMARY

17. On or about October 16, 2014, the Board received a complaint alleging that on July 15, 2014, Respondent Pharmacy dispensed two strengths of warfarin[1], a dangerous drug, from two different prescribers on the same day to the same patient, without clarification or notification to either prescriber.

18. In or about 2014, patient M.C. regularly received anticoagulation treatment at Olive View-UCLA Medical Center, Anticoagulation Clinic (the Clinic). Patient M.C. took daily warfarin tablets prescribed at the Clinic and was regularly and carefully monitored at the Clinic to make sure her blood PT and INR levels are in an appropriate range. PT and INR are laboratory tests used to monitor the effectiveness of the warfarin therapy.

19. On July 14, 2014, P.K., a Nurse Practitioner at the Clinic prescribed warfarin 2.5 mg tablets to patient M.C. The patient had been on this dose for more than one year and prescriptions were always written by a member of the Clinic. On July 15, 2014, Cardiologist P.S., MD, at Olive View-UCLA Medical Center, prescribed warfarin 5 mg tablets to patient M.C. The prescription was inadvertently doubled.

20. On July 15, 2014, patient M.C. received warfarin 5 mg tablets and warfarin 2.5 mg tablets at Respondent Pharmacy. Specifically, at 4:00 p.m. on July 15, 2014, prescription #792525 for 96 tablets of warfarin 5 mg, with directions to take one tablet daily, except 2 tablets on Wednesday, was verified by Respondent Marquez and filled and dispensed at Respondent Pharmacy for patient M.C. At 5:25 p.m., prescription #792497 for 45 tablets of warfarin 2.5 mg, with directions to take 1 tablet daily, except 2 tablets on Wednesday, was verified by Respondent Marquez and filled and dispensed at Respondent Pharmacy for patient M.C. Based on Respondent Pharmacy's records, prescription # 792497 and prescription # 792525 were picked up together at 5:27 p.m. on July 15, 2014, by patient M.C.'s agent.

[1] Warfarin (brand name, Coumadin) is an anticoagulant (blood thinner) prescription drug. It reduces the formation of blood clots. It is used to treat or prevent blood clots in veins or arteries, which can reduce the risk of stroke, heart attack, or other serious conditions. warfarin increases the risk of bleeding, which can be severe or life-threatening.

21. Dr. C.R. reported that patient M.C. first finished taking warfarin 2.5 mg tablets and then started taking the warfarin 5 mg tablets. Sometime after taking warfarin 5 mg tablets, patient M.C. developed multiple bruises all over her body and noticed blood in her urine. She was subsequently admitted to the hospital with an elevated INR of 11 and was hospitalized for two days.

22. On or about October 3, 2014, Dr. C.R. and P.K. contacted Respondent Pharmacy and spoke with Pharmacist S.A. to complain about the medication error. Respondent Pharmacy did not complete a quality assurance report upon discovering the medication error.

23. On or about October 16, 2014, Dr. C.R. filed a complaint against Respondent Pharmacy.

FIRST CAUSE FOR DISCIPLINE

(Failure to Review Drug Therapy and Patient Medication Record Prior to Delivery)

24. Respondent Pharmacy and Respondent Marquez are subject to disciplinary action under section 4301, subdivision (o), in conjunction with California Code of Regulation, title 16, section 1707.3, in that Respondents failed to review a patient's drug therapy and medication record before each prescription was delivered, and screen for severe potential drug therapy problems. Specifically, on July 15, 2014, Respondents dispensed prescription number 792497 and prescription number 792525, both for warfarin for patient M.C. without a pharmacist's review of the patient medical profile. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 17 through 23 above, as though set forth in full herein.

SECOND CAUSE FOR DISCIPLINE

(Failure to Verify Erroneous or Uncertain Prescriptions)

25. Respondent Pharmacy and Respondent Marquez are subject to disciplinary action under section 4301, subdivision (o), in conjunction with California Code of Regulation, title 16, section 1761, subdivision (a), in that they dispensed a prescription that contained a significant error, omission, irregularity, uncertainty, ambiguity or alteration and, upon receipt of such prescription, failed to contact the prescriber to obtain the information needed to validate the

prescription. Specifically, on July 15, 2014, Respondents filled and dispensed prescription number 792497 and prescription number 792525, both for warfarin, for the same patient from two different prescribers without contacting the prescribers to obtain the information needed to validate the prescriptions. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 17 through 24 above, as though set forth in full herein.

THIRD CAUSE FOR DISCIPLINE

(Failure to Establish/Participate in Quality Assurance Review)

26. Respondents Pharmacy and Respondent Marquez are subject to disciplinary action under section 4301, subdivision (o), in conjunction with California Code of Regulation, title 16, section 1711, subdivision (a), in that they failed to establish or participate in a quality assurance program, which documents and assesses medication errors to determine cause and an appropriate response as part of a mission to improve the quality of pharmacy service and prevent errors. Specifically, on or about October 3, 2014, Pharmacist S.A., while working at Respondent Pharmacy, was contacted by a prescriber and notified that prescriptions with two strengths of warfarin from two different prescribers were dispensed by Respondent Pharmacy on the same day to patient M.C. This dispensing took place without clarification or notification to either prescriber. Respondents failed to timely complete a quality assurance report upon discovering this medication error. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 17 through 25 above, as though set forth in full herein.

FOURTH CAUSE FOR DISCIPLINE

(Failure to Provide Consultation)

27. Respondent Pharmacy and Respondent Marquez are subject to disciplinary action under section 4301, subdivision (o), in conjunction with California Code of Regulation, title 16, 1707.2, subdivision (b)(1)(B), in that they failed to provide an oral consultation to a patient or patient's agent when a prescription drug that was not previously dispensed to the patient in the same dosage form, strength or with the same written directions was being dispensed by the pharmacy. Specifically, on July 15, 2014, Respondent Pharmacy, dispensed prescription number 792497 for warfarin 2.5 mg and prescription number 792525 for warfarin 5 mg. to patient M.C.'s

agent, which doubled the dose that was dispensed previously by the pharmacy. If an oral consultation had been provided, two prescriptions with different strengths for the same dangerous drug would not have been dispensed. Complainant refers to, and by this reference incorporates, the allegations set forth above in paragraphs 17 through 26 above, as though set forth in full herein.

DISCIPLINE CONSIDERATIONS

28. To determine the degree of discipline, if any, to be imposed on Respondent Marquez, Complainant alleges that on or about June 25, 2015, in a prior administrative action, the Board issued Citation Number CI 2014 65963 to Respondent Marquez and fined him $3,000, for violating California Code of Regulations, title 16, section 1714, subdivision (d) (failure to maintain operational standards and security). The underlying circumstances were as follows. From September 24, 2013, to April 9, 2014, while serving as the Pharmacist-in-Charge at CVS Pharmacy #9665 (PHY 47795), located at 5944 N. Figueroa Ave., Los Angeles, CA 90042, the pharmacy reported a loss of controlled substances due to employee pilferage. A Board audit found a loss of 14,400 ml of promethazine with codeine syrup and 829 tablets of alprazolam 2 mg between May 1, 2013, and January 21, 2014. That Citation is now final and is incorporated by reference as if fully set forth.

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PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Pharmacy Permit Number PHY 46783, issued to Garfield Beach CVS LLC dba CVS Pharmacy #4789;

2. Revoking or suspending Original Pharmacist License Number RPH 69427 issued to Omar Marquez;

3. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3;

4. Taking such other and further action as deemed necessary and proper.

DATED: 4/6/16

VIRGINIA HEROLD
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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